

Appl. No. 09/783,254
Amdt. dated April 27, 2004
Reply to Office Action of December 30, 2003

REMARKS/ARGUMENTS

Claims 38-60 have been examined. As an initial matter, Applicants note that claims 38-64 were pending in this case prior to issuance of the present office action. Applicants request the examination and status of remaining claims 61-64. Further, Applicants request that any further action issued in this case be made non-final so that Applicants may appropriately address these claims.

New claim 65 has been added. Claims 1-36 have been canceled. Applicants note with appreciation the allowance of claims 38-51 and 60. Re-examination and reconsideration of remaining claims 52-59 and 61-65 are respectfully requested.

Applicants further note that an information disclosure statement was filed with the U.S. Patent Office on April 8, 2004. Please send confirmation of the consideration of references in this statement prior to the next action.

Restriction Requirement

Applicants have canceled claims 1-36 without prejudice pursuant to a restriction requirement. Applicants reserve the right to pursue patent protection for these inventions in a subsequently filed application.

Rejection under 35 U.S.C. § 102

Claims 52-54 and 57-59 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,283,257 issued to Gregory et al. This rejection is traversed for the following reasons.

Independent claim 52 recites a method for inhibiting restenosis in a blood vessel following recanalization of the blood vessel. The method comprises implanting a vascular prosthesis comprising a scaffold having means thereon for releasing mizoribine in the blood vessel and releasing mizoribine and at least one other substance in addition to mizoribine from the prosthesis when implanted in the blood vessel so as to inhibit smooth muscle cell proliferation. This positive recitation of a scaffold having means thereon for releasing mizoribine has not been reasonably shown or suggested by the cited art.

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As the Examiner certainly knows and appreciates, a single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. §102. M.P.E.P. §2131; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the claim." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Gregory et al. is directed to the use of MPA in preventing hyperproliferative vascular disease. Gregory et al. discloses *in vivo* and *in vitro* examples of the effect of administration of MPA, cyclosporine (CsA), FK 506, rapamycin (RPM), and MPA in combination with RPM on the intimal thickening. All of the examples in Gregory et al. are limited to systemic administration of the drugs.

Gregory et al. provides no teaching or enablement whatsoever as to a method for inhibiting restenosis using mizoribine, and more particularly releasing mizoribine from a stent, as is currently claimed by claim 52. At best, Gregory et al. provides a speculative reference as to the potential use of mizoribine. Claim 52 requires "... implanting a vascular prosthesis comprising a scaffold having means thereon for releasing mizoribine in the blood vessel; and releasing mizoribine from the prosthesis into the blood vessel so as to inhibit smooth muscle cell proliferation." In contrast to the claimed invention, Gregory et al. does not teach or suggest a prosthesis comprising a scaffold having any means thereon for releasing mizoribine.

Applicants request, if the present rejection is maintained, that the Examiner show or explain where the Gregory et al. reference teaches or suggest the distinct structural limitation of a scaffold having means thereon for releasing mizoribine, as presently claimed in claim 52. "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Found. v. Genentech Inc.*, 18 USPQ 2d 1001, 1010 (Fed.

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Cir. 1991). Absent such a showing, Applicants respectfully request withdrawal of the 35 U.S.C. § 102 rejection and allowance of independent claim 52 (and dependent claims 53-59).

Added Claim

New claim 65 has been added. Support for this new claim can be found throughout the originally filed specification. The novel and non-obvious elements of this claim have not been shown or reasonably suggested in the cited art of record. As such, Applicants respectfully request allowance of new claim 65.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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